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09/037,657	03/10/1998	TRACY WILLSON	10857Z	7400

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EXAMINER	
HAMUD, FOZIA M	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 06/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/037,657	WILLSON ET AL.	
	Examiner	Art Unit	
	Fozia M Hamud	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *40,42-47 and 57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *40,42-47 and 57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1a. Receipt of Applicants' after final amendment and arguments filed on 19 November 2003 is acknowledged.

Status of Claims:

1b. Claims 1-39, 41, 48-56 have been canceled. Claims 40, 42-37 and new claim 57 are pending and under consideration.

2a. Upon further consideration, the examiner has decided to withdraw the finality of the previous office action (mailed on 20 October 2003). PROSECUTION IS HEREBY REOPENED. The indicated allowability of 43-48 is also withdrawn.

3. The following previous objections and rejections are withdrawn in light of Applicants amendment filed on 11/19/03:

(I) All of the rejections and objections made against cancelled claims 20-27 and 35-38 and 49-54 are withdrawn.

NEW REJECTIONS:

Claim Rejections - 35 U.S.C. §101/112

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4a. The rejection of claims 40, 42-47 made under 35 U.S.C. 101 is reinstated and new claim 57 is also rejected under the same statute, because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility. Instant claims are directed to an isolated hemopoietin receptor comprising the amino acid sequence set forth in SEQ NO:13, 15, 1 7, 1 9 or 25 and nucleic acid

encoding said receptor. The specification describes the polypeptides of SEQ ID N0: 13. 15, 17, 19, 25, as being a novel hemopoietin receptor, (page 3, lines 1 1-14). However, the instant specification does not disclose any information regarding the cognate ligand that binds to the claimed receptor, or any functional characteristics of the claimed hemopoietin receptor. The instant specification discloses that the claimed hemopoietin receptor is expressed in salivary gland, Lung and testis of the adult mouse, and that it is expressed in fetal tissues from day 10 of gestation through birth, however, it does not show the significance of this expression. The specification also discloses a knockout mouse and shows lack of this receptor is lethal during embryonic development or immediately after birth, (page 57, lines 5-10). However, the specification does not disclose any phenotype for the mice that lack this receptor, although it is apparent that this receptor is important, it is not clear why or what biological processes it is involved in. One asserted utility for the claimed hemopoietin receptor is the generation of a range of therapeutic molecules capable of modulating the expression of the receptor, such as agonists and antagonists, (page 15, lines 14-20). However, since it is not known what pathological conditions that this receptor is involved in and whether is up-regulated or down-regulated in these pathological processes, the skilled artisan would not know how to modulate it. While the instant specification discloses conventional protein administration techniques, it does not disclose which disease or diseases could the claimed receptor be used to treat, neither does it disclose any working examples. The specification establishes no connection between any pathological condition and the

claimed receptor, i.e, is the claimed receptor over expressed, under expressed or completely lacking in these diseases?

Therefore, without knowing the specific cytokine that binds to the claimed receptor, or the biological function of the claimed receptor, neither a substantial utility nor a specific utility can be established for the claimed polypeptide. The fact that the claimed polypeptide might belong to the hemopoietin receptor family is not enough to establish a substantial utility or a specific or well established utility for it. Although all the members of the hemopoietin receptor family are important, these receptors bind to diverse ligands with disparate functions. For example, interleukin-2 (IL-2) plays a role in immune response by causing proliferation of T lymphocytes and activated B lymphocytes and inducing pro-inflammatory cytokines such as IFN-K and TNF. On the other hand, erythropoietin is involved in anemia, because it stimulates formation of erythroid precursors to generate red blood cells. Thus, each receptor in this family performs a different but equally important function. Furthermore, Applicants have not disclosed the physiological role of the claimed receptor or the cognate ligand which binds it, nor have they established a nexus between said receptor and any disease or disorder.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4b. Claims 40, 42-47 and 57 are also rejected under 35 U.S.C. 1 12, first paragraph. Specifically, since the claimed invention is not supported by either a specific and

biology and molecular biology would immediately appreciate the utility of NR6 diagnostically and therapeutically.

Dr. Hilton's declaration is fully considered but is not found persuasive to provide either a specific and substantial asserted utility or a well established utility for the claimed receptors. Firstly, although the knockout mice data suggests that lack of this NR6 is lethal during embryonic development or immediately after birth, it is not clear how this would enable the use of this receptor in diagnostic manner. Applicants have not shown which birth defects could be diagnosed using the NR6 of the instant invention. The data from the knockout mice could not be extrapolated to the use of the NR6 receptor diagnostically, because there is no link established between this receptor and any birth defect. Furthermore, instant specification does not disclose which polypeptide was used to carry out the knockout mice experiments. Instant claims are drawn to polypeptide of SEQ ID NO: 13, 15, 17, 19 or 25. It appears that these are disparate sequences, for example SEQ ID NO:13 comprises 413 amino acid residues and is designated as murine NR6.1, SEQ ID NO:17 is designated as murine NR6.3 and comprises a 155 amino acid residues, while SEQ ID NO:19 comprises 278 residues and is artificial sequence and SEQ ID NO:25 comprises 350 amino acid resides and is designated as human NR6, (see table 3 on page 29). Thus, Example 15 on page 56 of the instant specification discloses the generation of knockout mice lacking NR6 receptor, however, there is no disclosure of which polypeptide sequence was used to generate said knockout mice. Instant specification does not clearly indicate whether

each of SEQ ID NO:13, 17, 15 or 25 was deleted to generate a knockout mice lacking that specific sequence.

Secondly, there is no disclosure in the instant specification that a decrease in NR6 results in reduced blood cell production. If there is post- filing data showing that a decrease in NR6 leads to a decrease in blood cells, while an increase in NR6 would lead to an increase in blood cells, Applicants must submit it. Furthermore, Applicants must submit which type of blood cells are decreased or increased and whether the decrease/increase of each of the claimed sequences leads to a decrease/increase of blood cells.

Thirdly, there is no dispute that the cytokine receptors are important family of proteins, however, Applicants do not demonstrate that having a WSXWS motif assures the claimed polypeptide with a utility common to all the members of this family. The fact that other members of this family have utility is irrelevant, since the physiological relevance of the claimed polypeptide as well as cognate ligand for each of the claimed receptors must be disclosed in order to meet the requirements under 35 U.S.C. §101.

Claim Rejections - 35 U.S.C. §112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 42 and 57 are rejected under 35 U.S.C. § 112 , second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5a. Claim 42 is drawn to an isolated haemopoietin receptor comprising an amino acid sequence encoded by a nucleic acid which hybridizes to SEQ ID NO:12, 14, 16, 18 or 28 and claim 57 is drawn to an isolated haemopoietin receptor comprising an amino acid sequence encoded by a nucleic acid which hybridizes to SEQ ID NO:24. However the specification discloses that, for example, SEQ ID NO:12 encodes SEQ ID NO:13, SEQ ID NO:14 encodes SEQ ID NO:15 and so forth and that SEQ ID NO:24 encodes the polypeptide of SEQ ID NO:25. Therefore, a nucleic acid that hybridizes to said sequence would not encode the desired polypeptide. It is suggested that the claims be amended to recite ".....encoded by a nucleic acid which hybridizes under .....to the *complement* of the nucleotide sequence of SEQ ID NO:12, 14....".

Conclusion:

6. No claim is allowed.

Advisory Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M Hamud whose telephone number is (571) 272-0884. The examiner can normally be reached on Monday, Thursday-Friday, 6:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Patent Examiner
Art Unit 1647
20 may 2004

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SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

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Remarks:

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